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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,676	12/26/2001	Crisanto Gutierrez-Armenta	4148-6	8375

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EXAMINER	
MEHTA, ASHWIN D	
ART UNIT	**PAPER NUMBER**
1638	

DATE MAILED: 09/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/025,676	GUTIERREZ-ARMENTA ET AL.	
	Examiner	Art Unit	
	Ashwin Mehta	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *4-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 18-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 December 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12262001*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicants' election of Group III, claims 1-3 and 18-21 in the reply filed on April 13, 2004 is acknowledged. Because Applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Information Disclosure Statement

2. The citation of the reference authored by Bo Shen et al. in the IDS submitted December 26, 2001 is lined through, because it is incomplete. It is suggested that Applicants resubmit the citation on another IDS with all of the information required by 37 CFR 1.98.

Priority

3. Applicants have not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows: An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

Specification

4. The specification fails to comply with the sequence rules of 37 CFR 1.821-1.825. The description of Figure 1 on pages 5-6 does not recite the sequence identifiers assigned to the sequences that appear in that figure. Nucleotide sequences also appear on page 6, lines 21, 22, and 34 which must be referred to by their sequence identifiers.

5. The specification in at least one location (page 7, lines 8-10) indicates the SEQ ID NO: 1 sets for the cDNA sequence of ZmRb1. However, the sequence listing submitted March 18, 2002 shows that SEQ ID NO: 1 is an amino acid sequence, and SEQ ID NO: 2 is a nucleotide sequence. Correction/clarification is required. New matter must be avoided.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-3 and 18-21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2, 4, and 5 of U.S. Patent No. 6,384,299.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the patented claims is encompassed by the instant claims. Instant claims 1-3 are directed to a method of controlling the growth of a plant cell or virus within that cell by increasing or decreasing the level and/or activity of any retinoblastoma (Rb) protein in the cell by incorporating any recombinant nucleic acid into the cell. Patented claim 2 is directed to a method of in which the level of retinoblastoma protein is increased in a plant cell by incorporating and expressing a recombinant nucleic acid encoding a Rb protein that that interacts with a viral LXCXE motif in a plant cell and inhibits plant virus replication. Instant claim 2 limits claim 1 by requiring the nucleic acid to increase or inhibit the expression of a Rb protein in the cell, and instant claim 3 limits the nucleic acid to express a Rb protein or fragment thereof that interacts with a viral LXCXE motif. Instant claims 18-21 are directed to a plant cell comprising a recombinant nucleic acid that encodes a Rb protein or a transgenic plant comprising said cell, as are patented claims 4 and 5. The nucleic acid encoding the Rb protein in patented claims 4 and 5 are limited to those encompassed by patented claim 1, whereas the instant claims encompass nucleic acids encoding any Rb protein. The instant claims encompass the scope of the patented claims. As the recombinant nucleic acid of the plant cell of patented claim 4 comprises a promoter that is operably linked to the sequence encoding the Rb protein, it is obvious that the Rb protein is expressed from the recombinant nucleic acid.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-3 and 18-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1: the recitation, "growth of a plant cell or a plant virus" renders the claim indefinite. It is not exactly clear what is meant by "growth" in the context of the claim. Is it meant that the size of the cell or virus is controlled, or division, etc.?

Further in claim 1: the recitation, "by incorporation of a recombinant nucleic acid" renders the claim indefinite. It is unclear that the kind of recombinant nucleic acid is to be incorporated into the cell.

In claims 2 and 3: it is not exactly clear what is meant by "characterised" in line 1. It is suggested that the recitation, "characterised in that" replaced with --wherein--.

Further in claims 2 and 3: the recitation, "such as to" renders the claim indefinite. It is not exactly clear what is meant by this recitation.

Further in claim 3: the recitation, "viral LXCXE motif" renders the claim indefinite. It is not exactly clear what the recitation is referring to. The specification indicates that the RepA protein of wheat dwarf virus contains an LXCXE motif (page 9, lines 8-10). If this is what the recitation in the claim is referring to, it is suggested that the recitation be replaced with --a protein of said virus that comprises an LXCXE motif,--.

In claims 18-20: it is not clear what is meant by "characterised" in the recitation, "characterised in that it comprises" in claims 18, 19, and 20 (it is assumed that "cornorises" in claim 19 should actually be "comprises"), in the recitation, "characterized in that it expresses" in claim 20. It is suggested that the recitation in claims 18, 19, and 21 be replaced with --

comprising--. In claim 20, it is suggested that the recitation be replaced with --wherein--, and the recitation, --is expressed-- be inserted in line 2 after "protein".

In claim 19: the recitation, "a recombinant nucleic acid as defined above" renders the claim indefinite. It is not clear what nucleic acid is being referred to.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-3 and 18-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn towards a method of controlling the growth of a plant cell or a plant virus within that cell, comprising increasing or decreasing the level and/or activity of a retinoblastoma protein, by incorporation therein of any recombinant nucleic acid; or wherein the nucleic acid increases or inhibits expression of any retinoblastoma protein in the cell; or wherein the nucleic acid expresses any retinoblastoma protein or peptide fragment thereof that interacts with a viral LXCXE motif without affecting the normal functioning of the cell; or a plant cell comprising a recombinant nucleic acid encoding a retinoblastoma protein; or a transgenic plant comprising said plant cell.

The specification indicates that a cDNA (SEQ ID NO: 2), isolated from a maize cDNA library, encodes a retinoblastoma (Rb) protein (SEQ ID NO: 1) termed "ZmRb1" (page 6, line 10 to page 7, line 21; while the specification, for example on page 7, indicates that SEQ ID NO: 1 is the ZmRb1 cDNA sequence, the sequence listing submitted March 18, 2002 shows that SEQ ID NO: 1 is an amino acid sequence). The specification indicates that ZmRb1 has segments homologous to the "A" and "B" pocket domains present in other retinoblastoma proteins; non-conserved N- and C- terminal domains; shares 28-30% overall homology to other retinoblastoma proteins, and 50-64% homology within the A and B domains; contains a cysteine residue that is known to be critical to the human Rb protein; a proline-rich domain spanning residues 561-577; and 16 consensus SP or TP sites known to be phosphorylation sites by cyclin-dependent kinases in other Rbs (page 8, line 9 to page 9, line 5). It was known that the human p130 protein can interact with the wheat dwarf virus (WDV) RepA protein through the LXCXE motif of the viral protein. ZmRb1 also interacted with the WDV RepA protein through this motif in a yeast two-hybrid assay (page 9, line 8 to page 10, line 24). This finding suggested to the inventors that, as in animal cells, sequestration of plant Rb by viral RepA promotes inappropriate entry into S phase, which is required for geminivirus replication in plant cells. To test ZmRb1 function in plant cells, plasmids comprising either the cDNA for ZmRb1 or a cDNA encoding a human retinoblastoma protein, p130, operably linked to the CaMV 35S promoter, were constructed and transfected into wheat cells. Replication of WDV plasmid DNA was impaired in the cells (page 10, line 25 to page 11, line 19).

However, the specification does not describe recombinant nucleic acids encoding any plant retinoblastoma protein other than those encoding ZmRb1 (SEQ ID NO: 1). The

specification does not correlate the activity of ZmRb1 with any other plant protein. While the specification describes the isolation of the cDNA encoding ZmRb1, this does not describe other products themselves. See Fiers vs. Sugarno, 25 USPQ 2d (CAFC 1993) at 1606, which states that "[a]n adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself". Also see Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016 at 1021 and 1027, (Fed. Cir. 1991) at page 1021, where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence). Given the breadth of the claims encompassing recombinant nucleic acids encoding any and all retinoblastoma proteins, and the lack of written description as discussed above, the specification fails to provide an adequate written description of the multitude of recombinant nucleic acids encompassed by the claims.

9. Claims 1-3 and 18-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of inhibiting replication of a plant virus comprising a protein comprising an LXXCXE motif within a plant cell, comprising introducing and expressing in the plant cells a recombinant nucleic acid encoding human retinoblastoma protein or SEQ ID NO: 1, does not reasonably provide enablement for method of controlling the growth of viruses in plant cells in other manners, methods of controlling the growth of plant cells, or recombinant nucleic acids encoding other plant retinoblastoma proteins. The specification does not enable any person skilled in the art to which it pertains, or with which it is

most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn towards a method of controlling the growth of a plant cell or a plant virus within that cell, comprising increasing or decreasing the level and/or activity of a retinoblastoma protein, by incorporation therein of any recombinant nucleic acid; or wherein the nucleic acid increases or inhibits expression of any retinoblastoma protein in the cell; or wherein the nucleic acid expresses any retinoblastoma protein or peptide fragment thereof that interacts with a viral LXCXE motif without affecting the normal functioning of the cell; or a plant cell comprising a recombinant nucleic acid encoding a retinoblastoma protein; or a transgenic plant comprising said plant cell.

The specification indicates that a cDNA (SEQ ID NO: 2), isolated from a maize cDNA library, encodes a Rb protein (SEQ ID NO: 1) termed "ZmRb1" (page 6, line 10 to page 7, line 21; while the specification, for example on page 7, indicates that SEQ ID NO: 1 is the ZmRb1 cDNA sequence, the sequence listing submitted March 18, 2002 shows that SEQ ID NO: 1 is an amino acid sequence). The specification indicates that ZmRb1 has segments homologous to the "A" and "B" pocket domains present in other retinoblastoma proteins; non-conserved N- and C-terminal domains; shares 28-30% overall homology to other retinoblastoma proteins, and 50-64% homology within the A and B domains; contains a cysteine residue that is known to be critical to the human Rb protein; a proline-rich domain spanning residues 561-577; and 16 consensus SP or TP sites known to be phosphorylation sites by cyclin-dependent kinases in other Rbs (page 8, line 9 to page 9, line 5). It was known that the human p130 protein can interact with the wheat dwarf virus (WDV) RepA protein through the LXCXE motif of the viral protein.

ZmRb1 also interacted with the WDV RepA protein through this motif in a yeast two-hybrid assay (page 9, line 8 to page 10, line 24). This finding suggested to the inventors that, as in animal cells, sequestration of plant Rb by viral RepA promotes inappropriate entry into S phase, which is required for geminivirus replication in plant cells. To test ZmRb1 function in plant cells, plasmids comprising either the cDNA for ZmRb1 or a cDNA encoding a human retinoblastoma protein, p130, operably linked to the CaMV 35S promoter, were constructed and transfected into wheat cells. Replication of WDV plasmid DNA was impaired in the cells (page 10, line 25 to page 11, line 19).

However, the specification does not teach recombinant nucleic acids encoding retinoblastoma proteins other than those encoding SEQ ID NO: 1. It is unclear how the sequence of SEQ ID NO: 1 may be changed without affecting its functional activity. Xie et al. (EMBO J., 1996, Vol. 15, pages 4900-4908) teach that ZmRb1 contains unique domain of unknown function (page 4906). It is then unclear, in the absense of further guidance, how SEQ ID NO: 1 may differ to yield other recombinant nucleic acids that still retain Rb function. Undue experimentation would be required by one skilled in the art to determine how SEQ ID NO: 1 may be changed without affecting its function. Also see In re Bell, 26 USPQ2d 1529, 1532 (Fed. Cir. 1993) and In re Deuel, 34 UPSQ2d, 1210 (Fed. Cir. 1995), which teach that the mere existence of a protein does not enable claims drawn to a nucleic acid encoding that protein. See also Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016 at page 1027, where it is taught that the disclosure of a few gene sequences did not enable claims broadly drawn to any analog thereof.

The specification also does not enable using the claimed method to control the growth of plant cells. While the specification speculates on the role of ZmRb1 in the regulation of the G1/S phase transition of plant cells, it does not teach that growth of plant cells can be controlled by increasing or decreasing the level and/or activity of retinoblastoma protein by incorporation of a recombinant nucleic acid. The specification includes a speculative discussion on whether the disruption of the Rb pathway would lead to a tumor-prone condition in plants. The inventors note that while the VirB4 protein of Ti plasmids contain an LXCXE motif, and that this protein is required for tumor induction, the role of the LXCXE motif in this context remains to be examined (page 12, lines 5-21). It is further noted that the specification does not teach that expression of p103 or ZmRb1 in wheat cells affected the growth of the cells. Further, while the specification speculates on the biological function of ZmRb1, the exact role and mechanism of action of ZmRb1 in the plant cell cycle was unknown at the time the invention was filed. In mammalian cells, Rb function is exerted by inhibiting E2F transcription factors (Xie et al., EMBO J., 1995, Vol. 14, pages 4073-4082, see page 4079). However, at the time of filing of the instant application, plant E2F homologs were not known. Xie et al. (1995) also stress that a picture of the nature of molecular mechanisms governing the cell cycle in plant cells is not available, unlike in mammalian cells (page 4079). Therefore, without knowledge of the exact role of ZmRb1 in cell growth, an in the absense of further guidance, undue experimentation would be required by one skilled in the art to express any random recombinant nucleic acid in plant cells and use the claimed method to control plant growth. See Genentech, Inc. v. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed.G Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Further, the specification does not teach that the growth of viruses in the plant cells comprising a recombinant nucleic acid expressing a retinoblastoma protein was controlled in any way other than inhibition of viral nucleic acid replication. One skilled in the art would not expect virus growth to increase in plant cells comprising a recombinant nucleic acid encoding a retinoblastoma protein, given that the specification teaches that wheat cells expressing p130 or ZmRb1 inhibited replication WDV plasmid DNA.

Furthermore, the specification does not teach how the activity, as opposed to the levels of retinoblastoma proteins may be increased or decreased, by incorporation of into a plant cell of any recombinant nucleic acid. The specification provides not guidance at all as to what proteins may be regulatory proteins or co-factors of ZmRb1 or any other plant retinoblastoma protein. At the time of filing, no other plant retinoblastoma proteins, or their regulatory proteins or co-factors, were known in the art. Undue experimentation would be required by one skilled in the art to determine the plant proteins that affect the activity of retinoblastoma proteins in plants, and clone the genes encoding them for use in the claimed method. See Genentech, Inc. v. Novo Nordisk, A/S, *supra*.

Further, as discussed above, p130 and ZmRb1 interact with the LXCXE motif of the WDV RepA protein, in order to inhibit its replication. It is therefore unpredictable that plant viruses that lack this essential binding motif in an essential replication protein can be controlled by the claimed method. Neither the specification nor the prior art teach retinoblastoma proteins that interact with viral proteins through other domains. In the absence of further guidance, undue experimentation would be required by one skilled in the art to control the plant viruses that

comprise proteins that do not have the LXCXE motif. See Genentech, Inc. v. Novo Nordisk, A/S, *supra*.

The specification also does not teach peptide fragments of any retinoblastoma protein that may be expressed in the claimed method to control plant growth and/or viral growth. While the specification indicates that ZmRb1 and p130 share conserved domains, it does not teach what peptide fragments of any Rb alone may be used to control plant cell or virus growth. Xie et al. (1996) teach that ZmRb1 contains conserved domains connected by non-conserved spacers (page 4901). It is unpredictable if ZmRb1 can function without these spacers. For example, in the absense of evidence to the contrary, it cannot be ruled out that the spacers are required for the protein to acquire a proper, active tertiary structure. Xie et al. (1996) also indicate that ZmRb1 contains domains not present in other Rb homologs and whose function is unknown (pages 4901, 4906). The specification does not teach what portions of ZmRb1 can interact with the LXCXE motif alone. Undue experimentation would be required by one skilled in the art to which among the numerous fragments retain Rb function. See Genentech, Inc. v. Novo Nordisk, A/S, *supra*. Given the breadth of the claims, unpredictability of the art and lack of guidance of the specification as discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

10. Claims 1-3 and 18-21 are rejected. Non-elected claims 4-17 are withdrawn from consideration.

Contact Information

Any inquiry concerning this or earlier communications from the Examiner should be directed to Ashwin Mehta, whose telephone number is 571-272-0803. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at 571-272-0804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

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September 21, 2004

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